K072126

SECTION 3

Summary of Safety and Effectiveness

Page 1 of (2)

OCT 2 2007

Sponsor: EMcision, Ltd.

Contact Person: Nagy Habib, MD
Chief Executive Officer
Liver Surgery Section, Hammersmith Hospital
Du Cane Road
London, W12 0NN
United Kingdom

Summary Prepared: 2007-08-21

Trade Name: Habib™ VesCoag

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification: Class II per 21 CFR 878.4400

Product Code: GEI

Predicate Devices: VNUS Closure™ System catheter manufactured by VNUS Medical Technologies Inc., San Jose, California, USA (K974521)

Intended Use:

The Habib™ VesCoag is a catheter intended to be used for the coagulation of blood vessels during general surgery.

Description:

The Habib™ VesCoag is a bipolar radiofrequency (RF) device that consists of a catheter, wire connections, hub, Y connector and two ring electrodes. The electrodes are configured with two rings creating proximal and distal heating zones. The Habib™ VesCoag has an attached cable which connects the device to an RF Generator. The catheter is inserted into the vessel and the tissue is coagulated using the RF power. The Habib™ VesCoag is designed for use in surgery and in imaging/radiological procedures and is a single use sterile device.

Technological Differences:

The Habib™ VesCoag has the same basic technological characteristics as the VNUS Closure™ System. Both devices use bipolar RF energy through a number of electrodes to coagulate vessels from the inside.

Performance Data:

Performance testing was undertaken to ensure that the Habib™ VesCoag functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMcision, Ltd.
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
455 E. Trimble Road
San Jose, California 95131

OCT 2 ˇ 2007

Re: K072126
Trade/Device Name: Habib™ VesCoag
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 18, 2007
Received: September 20, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

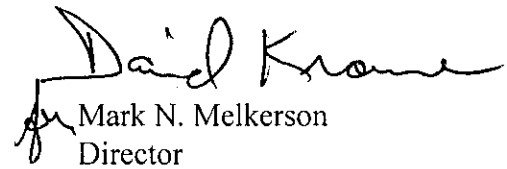
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(K) Number (if known) ~~Not yet Allocated~~ K072126

Device Name Habib™ VesCoag

The Habib™ VesCoag is a catheter intended to be used for the coagulation of blood vessels during general surgery.

Prescription Use ___X__ OR Over the Counter Use _____

(per 21 CFR 801.109)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072126